

# **EXHIBIT 1**

**Exhibit B - Materials Reviewed and Considered (Amended and Supplemental)**

- Third Amended Consumer Economic Loss Class Action Complaint, dated Nov. 1, 2021
- Expert Report of L. Plunkett, Ph.D., dated Oct. 31, 2022, and all documents cited therein
- Deposition of L. Plunkett, Ph.D., dated Jan. 12, 2023, and exhibits
- Expert Report of R. Najafi, Ph.D., dated Nov. 4, 2021
- Expert Report of R. Najafi, Ph.D., dated Oct. 31, 2022, and all documents cited therein
- Deposition of R. Najafi, Ph.D., dated Jan. 18 & 24, 2023, and exhibits
- Expert Report of S. Bain, dated Oct. 31, 2022, and all documents cited therein
- Deposition of S. Bain, dated Jan. 31, 2023, and exhibits
- Expert Report of S. Hecht, Ph.D., dated Oct. 31, 2022, and all documents cited therein
- Expert Report of S. Hecht, Ph.D., dated July 6, 2021
- Deposition of S. Hecht, dated Jan. 13, 2023, and exhibits
- P. Dong Deposition Transcript with Exhibits, dated Mar. 29, 2021
- P. Dong Deposition Transcript with Exhibits, dated Mar. 30, 2021
- P. Dong Deposition Transcript with Exhibits, dated Mar. 31, 2021
- P. Dong Deposition Transcript with Exhibits, dated Apr. 1, 2021
- P. Dong Deposition Transcript with Exhibits, dated Apr. 2, 2021
- J. Du Deposition Transcript with Exhibits, dated May 27, 2021
- J. Du Deposition Transcript with Exhibits, dated May 28, 2021
- E. Gu Deposition Transcript with Exhibits, dated Apr 5, 2021
- E. Gu Deposition Transcript with Exhibits, dated Apr. 6, 2021
- J. Ge Deposition Transcript with Exhibits, dated May 26, 2022
- J. Ge Deposition Transcript with Exhibits, dated May 27, 2022
- J. Ge Deposition Transcript with Exhibits, dated Apr. 27, 2021
- J. Ge Deposition Transcript with Exhibits, dated Apr. 28, 2021
- J. Ge Deposition Transcript with Exhibits, dated Apr. 29, 2021
- J. Ge Deposition Transcript with Exhibits, dated Apr. 30, 2021
- R. Gergis Deposition Transcript with Exhibits, dated Feb. 2, 2021
- M. Li Deposition Transcript with Exhibits, dated Apr. 20, 2021
- M. Li Deposition Transcript with Exhibits, dated Apr. 21, 2021
- M. Li Deposition Transcript with Exhibits, dated Apr. 22, 2021
- Q. Li Deposition Transcript with Exhibits, dated Apr. 13, 2021
- Q. Li Deposition Transcript with Exhibits, dated Apr. 14, 2021
- Q. Li Deposition Transcript with Exhibits, dated Apr. 15, 2021
- Q. Li Deposition Transcript with Exhibits, dated Apr. 16, 2021
- H. Wang Deposition Transcript with Exhibits, dated Mar. 10, 2021
- H. Wang Deposition Transcript with Exhibits, dated Mar. 11, 2021
- M. Zhang Deposition Transcript with Exhibits, dated Mar. 22, 2021
- M. Zhang Deposition Transcript with Exhibits, dated Mar. 23, 2021
- M. Zhang Deposition Transcript with Exhibits, dated Mar. 24, 2021
- M. Zhang Deposition Transcript with Exhibits, dated Mar. 25, 2021
- M. Zhang Deposition Transcript with Exhibits, dated Mar. 26, 2021
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- 21 C.F.R. § 210.1
- 21 C.F.R. § 210.3
- 21 C.F.R. § 211.100
- 21 C.F.R. § 211.186

- 21 C.F.R. § 211.188
- 21 C.F.R. § 314.3
- 21 C.F.R. § 314.420
- 21 C.F.R. § 314.50
- 21 C.F.R. § 314.70
- 21 C.F.R. § 314.94
- 21 C.F.R. § 314.97
- 21 C.F.R. § 320.1
- 21 C.F.R. §§ 7.1-7.59
- 21 C.F.R. §§ 7.3
- 21 U.S.C. § 351
- Chemical & Engineering News, NDMA, a contaminant found in multiple drugs, has industry seeking sources and solutions (available at: <https://cen.acs.org/articles/98/i15/NDMA-contaminant-found-multiple-drugs.html>)
- European Medicines Agency, Guideline on the Limits of Genotoxic Impurities (valid from Jan. 1, 2007 to Jan. 31, 2018) (available at: [https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-limits-genotoxic-impurities\\_en.pdf](https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-limits-genotoxic-impurities_en.pdf))
- European Medicines Agency, Questions and answers on the 'Guideline on the limits of genotoxic impurities' (valid from Sep. 24, 2010 to Jan. 31, 2018) (available at: [https://www.ema.europa.eu/en/documents/scientific-guideline/questions-answers-guideline-limits-genotoxic-impurities\\_en.pdf](https://www.ema.europa.eu/en/documents/scientific-guideline/questions-answers-guideline-limits-genotoxic-impurities_en.pdf))
- F. Sörgel et al., The contamination of valsartan and other sartans, part 1: New findings, 172 J Pharm Biomed Anal. 395, 396 (2019), doi: 10.1016/j.jpba.2019.05.022 (available at: <https://www.sciencedirect.com/science/article/abs/pii/S0731708519302183?via%3Dihub>)
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- FDA Q3A, Attachment 3 (available at: <https://www.fda.gov/media/71733/download>)
- FDA Q3A, Guidance for Industry Q3A Impurities in New Drug Substances (available at: <https://www.fda.gov/media/71727/download>)
- FDA Q7 Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients: Guidance for Industry (available at: <https://www.fda.gov/files/drugs/published/Q7-Good-Manufacturing-Practice-Guidance-for-Active-Pharmaceutical-Ingredients-Guidance-for-Industry.pdf>)
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- FDA Q9, Guidance for Industry Q9 Quality Risk Management (available at: <https://www.fda.gov/media/71543/download>)
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- ICH Q3A (available at: <https://database.ich.org/sites/default/files/Q3A%28R2%29%20Guideline.pdf>)
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- Expert Report of David L. Chesney, MSJ, dated Jan. 12, 2022
- D. Chesney Deposition Transcript with Exhibits, dated Mar. 21, 2022
- Expert Report of F. Xue, Ph.D, dated Dec. 22, 2022
- Deposition of F. Xue, Ph.D, dated Feb. 3, 2023

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PRINSTON00069234	PRINSTON00249260	ZHP01458452	
PRINSTON00069235	PRINSTON00249303	ZHP01458464	
PRINSTON00069236	PRINSTON00251094	ZHP01458470	
PRINSTON00069238	PRINSTON00251097	ZHP01458495	
PRINSTON00069239	PRINSTON00251151	ZHP01458518	
PRINSTON00069240	PRINSTON00251397	ZHP01458527	
PRINSTON00069241	PRINSTON00267057	ZHP01458535	
PRINSTON00069242	PRINSTON00274844	ZHP01458541	
PRINSTON00069243	PRINSTON00275082	ZHP01459244	
PRINSTON00069244	PRINSTON00275164	ZHP01459815	
PRINSTON00069245	PRINSTON00275311	ZHP01459829	
PRINSTON00069246	PRINSTON00276496	ZHP01459834	
PRINSTON00069275	PRINSTON00279740	ZHP01459881	
PRINSTON00069294	PRINSTON00280178		